



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,866	03/14/2002	R. Rex Denton	MWH-008US	5719
25106	7590	08/13/2004	EXAMINER	
GENAISSANCE PHARMACEUTICALS			SWITZER, JULIET CAROLINE	
5 SCIENCE PARK			ART UNIT	
NEW HAVEN, CT 06511			PAPER NUMBER	

1634

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,866

Applicant(s)

DENTON ET AL.

Examiner

Juliet C. Switzer

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-22 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1, 3-22, and 24-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

Art Unit: 1634

### **DETAILED ACTION**

This application is a 371 of PCT/US00/22175. Claims 2 and 23 were cancelled, claims 1, 3, 6, 7, 10, 17, 19, 21, 22, and 24, and claims 27-29 were added in a preliminary amendment. Thus, claims 1, 3-22, and 24-29 are currently pending and subject to a Lack of Unity as set forth herein.

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 3, 6, and 7, drawn to an isolated polynucleotide comprising a nucleotide sequence which is a polymorphic variant of an immunoglobulin E receptor beta chain gene, or a fragment thereof.

Group 2, claim(s) 4, 5, 8, and 9, drawn to recombinant organisms.

Group 3, claim(s) 10, drawn to polypeptide encoded by isogenes.

Group 4, claim(s) 11, drawn to antibodies that bind polypeptide encoded by isogenes.

Group 5, claim(s) 12, drawn to methods for screening drugs.

Group 6, claim(s) 13, 14, 15, and 16, drawn to genotyping oligonucleotides.

Group 7, claim(s) 17, 18, 19, 20, 27, 28, and 29, drawn to a genotyping method.

Group 8, claim(s) 21, drawn to a method for predicting a haplotype pair.

Group 9, claim(s) 22 and 23, drawn to a method for identifying an association between a trait and a haplotype.

Group 10, claim(s) 25, drawn to a computer system.

#### FURTHER LACK OF UNITY WITHIN THE GROUPS

For groups 1 or 2, the species are the 12 separate haplotypes listed in table 5.

Furthermore, for these groups, if elected, applicant should identify which of polymorphisms recited in claim 6 are relevant to the elected haplotype.

For groups 3, 4, or 5, the species are each of the different possible variants of the IL4R $\alpha$  polypeptide. Applicant should identify a particular variant of the polypeptide and the isogene(s) that encode the elected polypeptide since some isogenes may encode the same polypeptide.

For group 6, the species are each of the possible combinations of genotyping oligonucleotides. If this groups is elected, please identify the PS sites to be included in the group, as well as the relevant SEQ ID NO: numbers.

For group 7, the species are each of the haplotypes listed in Table 5.

For group 9, the species are each of the haplotypes listed in Table 5 and each of the haplotype pairs listed in Table 4.

2. The inventions listed as Groups 1-10, and the further recited within group inventions, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Immunoglobulin E receptor beta chain genes that are polymorphic variants were known in the prior art at the time the invention was made (see, for example, Dickson *et al.*, and Hill *et al.*, both as cited in the IDS) who teach polymorphic variants of the IGERB gene, isolated polypeptides comprising the variants, methods for genotyping to determine the presence of the variants and oligonucleotides useful for such analysis. Furthermore, it is noted that the instant claim 1 refers to an isolated nucleic acid that is a polymorphic variant of IL4R $\alpha$ , or a fragment thereof, but does not require that the fragment overlap with a polymorphic region. Hill *et al.* and

Art Unit: 1634

Dickson *et al.* provide fragments of IL4R $\alpha$  polymorphic variants (p. 366). Further still, the claim of instant claim 1 encompasses an oligonucleotide having the reference polymorphic sequence (instant SEQ ID NO: 1), which applicant has taught in the specification was known at the time the invention was made. Also, claims 7 and 10 both encompass previously disclosed cDNA and amino acid sequences as these encompass the cDNA and encoded polypeptide relating to haplotype 7 which is the previously disclosed sequence (as taught in the specification). Thus, for at least these reasons, there is no special technical feature which joins the claimed inventions.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is required, in reply to this action, to elect a group for examination. The reply must also identify the claims readable on the selected group, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached by calling (571) 272-0782.

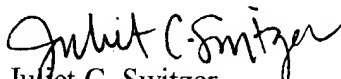
The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this

Art Unit: 1634

application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
Juliet C. Switzer  
Examiner  
Art Unit 1634

August 10, 2004